

### **IN THE SPECIFICATION**

On p. 11 please correct the title of Example 1 by changing “Vitro” to –Vivo–. The experiment was obviously done in an animal model.

### **REMARKS**

Claims 1-17 are pending in the application. All claims stand rejected under 101 and 101/112 grounds. The applicants request reconsideration of the rejections in the light of the following submissions and discussion.

#### **Specific and Substantial Utility**

According to Fed. Reg. 66: II(A)(01/05/2001) and MPEP §2107 II, an invention has a specific and substantial utility if one of average skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention, and the invention is specific, substantial and credible. According to the Primary Examiner at the Interview, substantial, credible utility can be established by a showing that others in the contemporaneous art have tried, and failed, to accomplish what the present invention has. Credibility is also assessed by declarations from experts, test data, and patents and printed publications (Fed. Reg. 66:(II)(A)(2)(2). Further, methods for identifying compositions that themselves have a “substantial utility” define a “real world” use (MPEP §2107.01 I).

The following are synopses of several of a great many contemporaneous US patents and printed publications that demonstrate that those of average skills in the art would recognize the present invention as having important usefulness: